

TAM:JHK  
F.#2012V01143

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK  
- - - - -X

UNITED STATES OF AMERICA,  
  
Plaintiff,  
  
- against -

UNDETERMINED QUANTITIES OF VARIOUS  
ARTICLES OF FOOD (DIETARY SUPPLEMENTS)  
AND DRUGS LABELED, OR OTHERWISE  
IDENTIFIED AS FOLLOWS: DR. BRAIN,  
pH BALANCE, FE-MON-9, GLUCOSAMINE PLUS  
PROSTATE-7

and

UNDETERMINED QUANTITIES OF ARTICLES OF  
DRUG LABELED, OR OTHERWISE IDENTIFIED  
AS FOLLOWS: FULL-BLOOM,

Defendants.

- - - - -X

Plaintiff, United States of America, by its attorney,  
Loretta E. Lynch, United States Attorney for the Eastern District  
of New York, James H. Knapp, Assistant United States Attorney, of  
counsel, alleges upon information and belief as follows:

NATURE OF THE ACTION

1. This is an in rem action to condemn and forfeit to  
the United States of America all of the above-referenced articles  
of food (dietary supplements) and drugs (hereinafter, the  
"articles" or "defendant articles") for violations of the Federal

**FILED**  
IN CLERK'S OFFICE  
U.S. DISTRICT COURT E.D.N.Y.

★ SEP 14 2012 ★

LONG ISLAND OFFICE

VERIFIED COMPLAINT IN REM

Civil Action No.  
12 CV

( , J.)  
( , M.J.)

**CV 12 4623**

**SPATT, J.**

**BROWN, M. J.**

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Food, Drug and Cosmetic Act ("Act"), 21 U.S.C. § 301, et seq.

2. The defendant articles are located at Confidence, Inc. ("Confidence"), 138 Haven Avenue Suite 101, Port Washington, New York, and consist of, in whole or in part, components that were shipped in interstate commerce from outside the State of New York.

#### JURISDICTION AND VENUE

3. Plaintiff brings this action in rem to condemn and forfeit the defendant articles. This Court has jurisdiction over an action commenced by the United States under 28 U.S.C. § 1345 and 21 U.S.C. § 334, which provides the Court with jurisdiction over forfeiture actions brought under the Act.

4. Venue lies in the Eastern District of New York pursuant to 28 U.S.C. §§ 1355 and 1395, and 21 U.S.C. § 334(a)(1), because the articles are located at Confidence, Inc., 138 Haven Avenue Suite 101, Port Washington, New York.

#### BASIS FOR FORFEITURE

5. As described more fully below, although labeled as dietary supplements, certain of the articles (DR. BRAIN, pH BALANCE, Fe-Mon-9, Glucosamine Plus, and PROSTATE-7) are also drugs within the meaning of 21 U.S.C. 321(g), because they are promoted for use in the diagnosis, cure, mitigation, treatment, and prevention of disease, as defined in the Act.

6. The article, Full-Bloom, is a drug within the

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meaning of 21 U.S.C. 321(g), because it is an article (other than food) intended to affect the structure and function of the body of man, as defined in the Act.

7. All of the defendant articles are "new drugs" within the meaning of 21 U.S.C. 321(p), because they are not generally recognized by qualified experts as safe and effective under conditions of use recommended or suggested in their labeling.

8. As "new drugs" within the meaning of 21 U.S.C. § 321(g), they may not be introduced or delivered for introduction into interstate commerce unless they are the subject of approved new drug applications under 21 U.S.C. § 355(b) or (j), or they are exempt from such requirements under 21 U.S.C. § 355(i). There are no such approved applications or exemptions in effect for any of the articles. See 21 U.S.C. § 355(a).

9. The articles of drugs are misbranded when offered for sale after shipment of one or more of their components in interstate commerce, within the meaning of the Act, 21 U.S.C. § 352(f)(1), in that their labeling fails to bear adequate directions for use and they are not exempt from such requirements under 21 C.F.R. § 201.115 because the articles are unapproved new drugs.

10. The articles of dietary supplement are adulterated when offered for sale after shipment of one or more of their

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components in interstate commerce, within the meaning of the Act, 21 U.S.C. § 342(g)(1), in that they have been prepared, packed, and held under conditions that do not meet current Good Manufacturing Practice (cGMP) regulations at 21 C.F.R., Part 111.

11. By reason of the foregoing, the articles are held illegally within the jurisdiction of this Court and are liable to seizure and condemnation and forfeiture pursuant to 21 U.S.C. § 334.

#### FACTS

12. Confidence, Inc. ("Confidence"), is an own-label distributor of various dietary supplement products that it has contract manufactured for it by a company in New Jersey.

13. Confidence makes disease claims for the defendant articles by word-of-mouth, direct mailing ads, television broadcast, brochures, and advertisements posted on the company's website [www.confidenceusa.com](http://www.confidenceusa.com). The products are sold both to retail stores and directly to customers via the Internet.

14. Disease claims made by Confidence for the defendant articles include, but are not limited to, the following:

(a) for "Senile Dementia," "prevention of brain atrophy" and for improving "memory and cognitive abilities" in Alzheimer's patients (DR.BRAIN);

(b) for maintaining "healthy cholesterol levels

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in blood" and for "diabetes induced occurrences such as Atherosclerosis, Kidney Dysfunction, Gangrene" (pH Balance);

(c) for "Frequent or Burning Urination," "joint discomfort, swelling" and "Depression" (Fe-Mon-9);

(d) for "Osteoarthritis of Hip Joint," to "rebuild and strengthen damaged joints" and to "fight off pain" (Glucosamine Plus);

(e) to "control prostate size," "promote a healthy prostate gland size due to inflammation, [to] reduce[s] urinary frequency, urgency, and dysuria" and "[to] prevent and treat cancers of the lung, prostate, stomach, bladder, cervix, skin, especially, prostate" (PROSTATE-7); and

(f) and for "rapid breast tissue growth, increas[ing] collagen synthesis and larger, more balanced breasts," "breast tissue development and firm[ing] the skin area around sagging breast" (Full-Bloom).

15. Following a United States Food and Drug Administration ("FDA") inspection conducted between October 25 and November 2, 2010, the FDA issued a Warning Letter to Confidence on July 7, 2011. The Warning Letter advised Confidence that claims in its product labels, accompanying promotional literature, and on its website, cause its products to be unapproved new drugs and misbranded drugs. The Warning Letter also cited Confidence for violations of the cGMP regulations for

dietary supplements.

16. In a response dated July 15, 2011, Confidence stated that it was "aggressively implementing appropriate actions, procedures, and guidelines" to meet cGMP. The letter also stated that the firm was in the process of establishing specifications and written procedures relevant to its business operations, and was re-establishing product labels, accompanying literature, and its website to be compliant with the Dietary Supplemental Health and Education Act ("DSHEA") to ensure that its products would not be classified as drugs.

17. During a follow-up FDA inspection conducted between January 10 and 26, 2012, FDA investigators found that Confidence continued to violate the cGMP regulations for dietary supplements and to make claims its products treated and/or prevented diseases. Significant deviations from the cGMP regulations for dietary supplements included the following:

(a) Failure to ensure that finished batches of product met product specifications, as required by 21 C.F.R. § 111.75(c);

(b) Failure to conduct an appropriate test or examination to verify the identity of any product ingredients, as required by 21 C.F.R. § 111.75(a)(1)(i);

(c) Failure to establish component specifications for the capsules used with the dietary supplements, as required

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by 21 C.F.R. § 111.70(b); and

(d) Failure to establish specifications for product labels or packaging, as required by 21 C.F.R. 111.70(d).

18. During a subsequent follow-up inspection, conducted between July 7 and July 13, 2012, FDA investigators found that Confidence continued to violate the cGMP regulations for dietary supplements and to make drug claims for its products. Significant deviations from the cGMP regulations for dietary supplements included, but were not limited to, the following:

(a) Failure to verify that finished batches of dietary supplements meet product specifications for identity, purity, strength, composition, and limits on contamination that may adulterate or lead to adulteration of the dietary supplement, as required by 21 C.F.R. § 111.75(c);

(b) Failure to qualify a supplier of a component by establishing the reliability of the supplier's certificate of analysis through confirmation of the results of their tests or examinations, as required by 21 C.F.R. § 111.75(a)(2)(ii)(A);

(c) Failure to conduct at least one appropriate test or examination to verify the identity of a dietary ingredient, prior to its use, as required by 21 C.F.R. § 111.75(a)(1)(i); and

(d) Failure to maintain documents of how suppliers of components are qualified, as required by 21 C.F.R.

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§ 111.75(a)(2)(ii)(C).

**CLAIM FOR RELIEF**

19. Plaintiff repeats and re-alleges each and every allegation set forth in paragraphs 1 to 18 above.

20. As a result of the foregoing, the articles are liable to seizure, condemnation, and forfeiture in accordance with 21 U.S.C. § 334.

WHEREFORE, Plaintiff requests that the Court issue a warrant and summons for the arrest and seizure of the articles; that notice of this action be given to all persons who reasonably appear to be potential claimants of the articles; that the articles be condemned and forfeited to the United States; that the articles be disposed of as this Court may direct pursuant to the provisions of the Act; and that the plaintiff be awarded its costs and disbursements in this action, and for such other and further relief as this Court deems proper and just.

Dated: Central Islip, New York  
September 14, 2012

LORETTA E. LYNCH  
United States Attorney  
Eastern District of New York  
Attorney for the United States  
610 Federal Plaza  
Central Islip, New York 11722

By: \_\_\_\_\_

JAMES H. KNAPP  
Assistant U.S. Attorney  
Attorney for Plaintiff  
(631) 715-7879


VERIFICATION

I, Kristen C. Jackson, declare that I am a Compliance Officer with the Food and Drug Administration, that I have read the foregoing Verified Complaint In Rem and know the contents thereof, and that the same is true to my own knowledge, except as to those matters therein stated to be alleged upon information and belief, and that as to those matters I believe them to be true.

That the sources of my information and the grounds of my belief are the official records and files of the United States.

I declare under penalty of perjury that the foregoing is true to the best of my knowledge, information and belief.

Dated: Central Islip, New York  
September 14, 2012

  
Kristen C. Jackson  
Compliance Officer  
Food and Drug Administration